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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/538,927   | 06/13/2005  | Hisayoshi Fujiwara   | FUJIWARA3           | 5998             |
| 1444   | 7590        | 02/13/2008           | EXAMINER            |                  |
| BROWDY AND NEIMARK, P.L.L.C.<br>624 NINTH STREET, NW<br>SUITE 300<br>WASHINGTON, DC 20001-5303 |             |                      | XIE, XIAOZHEN       |                  |
|  |             | ART UNIT             | PAPER NUMBER        |                  |
|  |             | 1646                 |                     |                  |
|  |             | MAIL DATE            | DELIVERY MODE       |                  |
|  |             | 02/13/2008           | PAPER               |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 10/538,927             | FUJIWARA ET AL.     |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | XIAOZHEN XIE           | 1646                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 11 December 2007.  
 2a) This action is FINAL.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-4 and 8 is/are pending in the application.  
 4a) Of the above claim(s) 8 is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1-4 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on 13 June 2005 is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

|  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### ***Response to Amendment***

Applicant's amendment of the claims filed on 11 December 2007 has been entered.

### ***Election/Restrictions***

Applicant requests rejoinder of claim 8 (Group II) in view of the argument with regard to the Morgan reference. Applicant argues that claim 8 shares a special technical feature with claims 1-4 of Group I.

Applicant's arguments have been fully considered but have not been found to be persuasive. The argument with regard to the Morgan reference is addressed below. Morgan teaches each and every limit of claim 1, and therefore, anticipates the instant invention. Since the 1<sup>st</sup> claimed invention (claim 1) has no special technical feature, it can not share a special technical feature with the other claimed inventions. Because the unity of invention is lacking, the PCT rules do not provide for the examination of multiple inventions in one application. Therefore, Group II (claim 8) can not be rejoined with Group I.

Claims 5-7 and 9-11 are cancelled. Claims 1-4 and 8 are pending. Claim 8 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions. Claims 1-4 are under examination.

### ***Claim Rejections Withdrawn***

The rejection of claims 1-4 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement for any colony-stimulating factor (CSF), is withdrawn in response to Applicant's amendment of the claims to recite G-CSF.

The rejection of claims 1-5 and 9-11 under 35 U.S.C. 102(b) as being anticipated by Cohen et al (WO 98/27995), is withdrawn in response to Applicant's amendment of the claims to limit G-CSF as the sole active ingredient.

***Claim Rejections Maintained***

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The amended claims 1-4 remain rejected under 35 U.S.C. 102(b) as being anticipated by Morgan et al. (Clin. Cancer Res., 1997, 3:2337-2345), for reasons set forth in the previous office action.

Applicant argues that although Morgan discloses the therapeutic activity of G-CSF in patients with metastatic breast cancer, Morgan does not teach any therapeutic effect of G-CSF on congestive cardiomyopathy. Applicant argues that Morgan discloses that patients may be safely treated with dose-intensive doxorubicin therapy without fear of unsuspected severe myofibrillar damage due to anthracyclines. Applicant argues that

Morgan does not treat patients with non-ischemic heart failure and therefore cannot anticipate the presently claimed invention.

Applicant's arguments have been fully considered but have not been found to be persuasive.

The independent claim 1 recites "a method for treating non-ischemic heart failure comprising administering to a patient in need thereof G-CSF as the sole active ingredient in an amount effective for treating non-ischemic heart failure". Morgan teaches that the primary limitation of cancer chemotherapeutic drugs, doxorubicin and anthracyclines, has been dose-dependent cardiac toxicity, which can result in a congestive cardiomyopathy due to myocyte loss (pp. 2343, right column, 2<sup>nd</sup> paragraph in Discussion). Thus, the patients in the Morgan reference who are under the chemotherapy, meet the limitation as "in need thereof". Morgan et al. teach the use of G-CSF for hematological support. Morgan teaches that administration of G-CSF (Filgrastim) began on day 6, following doxorubicin (given as a 96 h continuous i.v. infusion on days 1-4), and cyclophosphamide (given over 2 h on day 5) treatments (see Abstract). Thus, G-CSF was the sole active ingredient administered to the patient beginning on day 6. The fact that no patient developed severe myofibrillar damage shows the amount is effective. Therefore, Morgan meets each and every limitations of the claims.

***Double Patenting***

The amended claims 1 and 2 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 17 of copending Application No: 10/924,197.

Applicant argues that because the claim rejections are obviated, and this nonstatutory ODP rejection over a later-filed application 10/924,197 is the only rejection remaining, accordingly, this provisional ODP rejection should be withdrawn to permit the present earlier-filed application to issue as a patent without a terminal disclaimer.

Applicant's arguments have been fully considered but have not been found to be persuasive. Applicant's amendment of the claims has not overcome all remaining rejections (see *supra*). Therefore, this provisional ODP rejection can not be withdrawn.

***Conclusion***

NO CLAIM IS ALLOWED.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Xiaozhen Xie, Ph.D whose telephone number is 571-272-5569. The examiner can normally be reached on M-F, 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary B. Nickol, Ph.D. can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Xiaozhen Xie, Ph. D.  
February 5, 2008

/Elizabeth C. Kemmerer/

Primary Examiner, Art Unit 1646